K092911

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

APR 2 6 2010

Submitter's name:	Diazyme Laboratories
Submitter's address:	12889 Gregg Court Poway, CA 92064 USA
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Date the Summary was Prepared:	April 13, 2010
Name of the Device	SMART HbA1c Assay Reagent Kit SMART HbA1c Assay Control Kit SMART Analyzer
Trade Name:	SMART HbA1c Assay Reagent Kit SMART HbA1c Assay Control Kit SMART Analyzer
Common/Usual Name	Assay: Test system, Glycated hemoglobin A1c Instrument: Discrete photometric chemistry analyzer for clinical use
Device Classification Name	Glycosylated Hemoglobin Assay
Product code:	LCP, Glycosylated Hemoglobin JJX, Quality Control Material JJE, Analyzer, Chemistry (Photometric, Discrete) for Clinical use
Submission Type	510k
Regulation Number	864.7470, Glycosylated Hemoglobin Assay 862.1660, Quality Control Material 862.2160, Discrete Photometric Chemistry Analyzer for Clinical use

Device Class	I (Controls), II (Assay)
Predicate Device:	The SMART HbA1c Assay is substantially equivalent to the currently marketed Diazyme Direct Enzymatic HbA1c Assay (k070734).
Manufacturing Address	Diazyme Laboratories 12889 Gregg Court Poway, CA 92121 USA
Establishment Registration	2032900

Description of the Device:

SMART HbA1c Assay Kit contains reagents intended for use with the SMART HbA1c analyzer for the quantitative determination of stable HbA1c in human whole blood samples. Measurement of hemoglobin A1c is a valuable indicator for long-term diabetic control. SMART HbA1c assay reagents are similar to the predicate Direct Enzymatic HbA1c assay reagents (k070734). The similarities and differences in composition and format are noted in Table 1 below. The SMART HbA1c test is an enzymatic assay in which lysed whole blood samples are subjected to extensive protease digestion with Bacillus *sp* protease. This process releases amino acids including glycated valines from the hemoglobin beta chains. Glycated valines then serve as substrates for specific recombinant fructosyl valine oxidase (FVO) enzyme, produced in *E. coli*. The recombinant FVO specifically cleaves N-terminal valines and produces hydrogen peroxide. This, in turn, is measured using a horseradish peroxidase (POD) catalyzed reaction and a suitable chromagen. The HbA1c concentration is expressed directly as %HbA1c by use of a lot specific calibration curve that is stored in an RFID card provided with each SMART test kit. The manufacturer of the SMART HbA1c Assay kit is Diazyme Laboratories.

SMART HbA1c Assay Control Kit is intended for use as quality controls for the SMART HbA1c Assay Reagents and is packaged separately. The QC materials were pre market cleared with predicate device (k070734, k050178) and each lot of SMART HbA1c control kits will be tested with the SMART system during value assignment. The quality controls assist laboratory users in verification steps ensuring that the assay reagents are functioning correctly. QC materials are run exactly as samples. Users are instructed to verify the calibration curve with the controls and run controls each time a new lot of reagents are received. If QC materials fall outside laboratory acceptable range, users are instructed to re-test and call manufacturer customer service if problem persists. The manufacturer of the SMART HbA1c Assay Control kit is Diazyme Laboratories.

SMART HbA1c analyzer is a compact cuvette based spectrophotometer (10 inches x 5.5 inches x 5.5 inches) machine for point-of-care testing designed to analyze readings from single use reagent cuvettes. The instrument only uses the Diazyme Reagent System (DRS) cuvettes and caps and performs assay with a preprogrammed Radio Frequency ID (RFID) card. The DRS

cuvette is supplied prefilled with R1a and the DRS cap is supplied prefilled with R2. The DRS cuvette and caps are kept separate until use. Users are instructed (see proposed labeling) to prepare hemolysate samples in micro tubes prefilled with Lysis buffer and prepare R1ab mix by transferring R1b from supplied bottle to cuvette. Users are then instructed to transfer hemolysate to cuvette, snap in place DRS cap and insert into analyzer. The instrument warms the cuvette to 37C and after a predefined period adds the second reagent found in the DRS cap. The reagents and samples are mixed magnetically and absorbance readings are taken at 700nm. The lot specific RFID card contains reagent addition time, mixing time, reading time and calibration curve.

The SMART analyzers are manufactured for Diazyme Laboratories by Eurolyser Diagnostica, GMBH (**Eurolyser Diagnostica GmbH**, Bayernstraße 11a, 5020 Salzburg, AUSTRIA; www.eurolyser.com; Fon: +43 662 432100; Fax: +43 662 432100 50). Eurolyser Diagnostica, GMBH establishment registration number is 3006490192. Eurolyser Diagnostica developed and commercialized the SMART analyzers in Europe with their contract manufacturing partner AKATech, GMBH (**AKAtech Produktions- und Handels GmbH**, Untermühlberg 1, 4890 Frankenmarkt, AUSTRIA; http://www.akatech.at/en/index.php?option=com_content&task=view&id=31&Itemid=66; Tel.: +43 (7684) 88 04-0; Fax: +43 (7684) 88 04-9). AKATech is ISO13485 and ISO 9001 quality system certified.

The SMART HbA1c Analyzer System thus consists of the following:

1. SMART HbA1c Assay Kit. Reagents are provided in prefilled tubes, cuvettes and cuvette caps. The DRS cuvette and cuvette caps can only work with the SMART HbA1c analyzer.
2. SMART HbA1c Assay Control Kit. Controls are provided for quality control of the SMART Hba1c assay
3. SMART Analyzer. SMART analyzer is a compact cuvette based spectrophotometer machine for point-of-care testing, designed to analyze readings from single use SMART reagent cuvettes.

Indications for Use:

SMART Hemoglobin A1c (Glycated hemoglobin A1c; A1c; HbA1c) reagents are intended for use with the SMART analyzer for the quantitative determination of stable HbA1c in human capillary and venous whole blood samples. Measurement of hemoglobin A1c is a valuable indicator for long-term diabetic control. For *in vitro* diagnostic use only.

SMART HbA1c Assay Controls are intended for use as quality controls for the SMART HbA1c Assay reagents. For *in vitro* diagnostic use only.

SMART analyzer is a compact cuvette based spectrophotometer machine for point-of-care use, designed to analyze readings from single use SMART reagent cuvette. The SMART Analyzer System, consisting of the SMART Analyzer, SMART HbA1c reagent kit and SMART HbA1c Assay Controls, is for *in vitro* diagnostic use only.

Table 1 Summary of Assay Kit Components

Diazyme Direct Enzymatic HbA1c Assay Kit (predicate k070734)	**SMART HbA1c Assay Kit**
Kit can be used on automated chemistry analyzers using validated parameters	Kit can ONLY be used with SMART HbA1c analyzers
Lysis buffer 1 bottle • 100mM CHES • 1% Triton X-100 • 0.45% SDS • 0.5mM Redox agents	Lysis buffer 20 micro centrifuge tubes (prefilled) • 100mM CHES • 1% Triton X 100 • 0.45% SDS • 0.5mM Redox agents • <0.1% antifoam
Reagent 1 a 1 bottle • 5mM MES buffer • 4KU/mL Proteases • 0.5% Triton X-100 • >10μM Redox agents	Reagent 1a 20 DRS cuvettes (prefilled) • 5mM MES buffer • 4KU/mL Proteases • 0.5% Triton X-100 • >10μM Redox agents
Reagent 1 b • 1mM MES • <3mM Redox agent	Reagent 1 b • 1mM MES • <7mM Redox agent • <0.1% Brilliant Blue • 0.1% Triton X-100
Reagent 2 1 bottle • 15 mM Tris pH 8.0 • >10 U/mL FVO enzyme • 90U/mL POD • 0.8mM Chromagen	Reagent 2 20 DRS caps (prefilled) • 15 mM Tris pH 8.0 • >10 U/mL FVO enzyme • 90U/mL POD • 0.8mM Chromagen
Calibrator set	Calibrator
1 x 0.5mL Calibrator 1	1 x preprogrammed lot specific RFID card in each kit
1 x 0.5mL Calibrator 2	
Control Set	Control Set
1 x 0.5mL Control 1	1 x 0.5mL Control 1
1 x 0.5mL Control 2	1 x 0.5mL Control 2

Performance Testing Summaries:

Precision Study Summary

The precision of the SMART HbA1c Assay was evaluated according to Clinical and Laboratory Standards Institute (CLSI) EP5-A guideline with the following modifications: In the study, two unaltered whole blood specimens containing 5.6% and 7.4% HbA1c, one whole blood based HbA1c control containing 11.5% HbA1c were tested with 2 runs per day with duplicates over 10 working days. Reagent Lot 1 was used over the first 5 days and Reagent Lot 2 was used over the remaining 5 days. Both lots of reagents were used on three different SMART HbA1c analyzers. The precision evaluation data are listed below:

The mean value (Mean), standard deviation, within run imprecision and total imprecision CV% are calculated and summarized in the following tables:

Within Run precision CV%

	5.6% HbA1c	7.4% HbA1c	11.5% HbA1c
Total data points	40	40	40
Mean (%)	5.4	7.4	11.4
SD (%)	0.13	0.22	0.13
CV%	2.4%	3.0%	1.2%

Total Precision CV%

	5.6% HbA1c	7.4% HbA1c	11.5% HbA1c
Total data points	40	40	40
Mean (%)	5.4	7.4	11.4
SD (%)	0.15	0.19	0.15
CV%	2.70%	2.50%	1.30%

The precision of the SMART HbA1c assay was also evaluated in three physician office laboratories (POL) by trained medical technicians to test systemic and random error on three different Diazyme HbA1C SMART analyzers. Two unaltered human whole blood HbA1c specimens containing about 5.5%, 7.5% of HbA1c and one whole blood based control containing 11.5% HbA1c were used. For the three levels of samples tested at the three POL sites, the Diazyme Enzymatic HbA1c SMART assay yielded acceptable precision of CV $\leq$ 5%.

Between instrument precision and lot-to-lot variation imprecision studies were also performed on SMART Hba1c analyzers using a panel of 10 blood samples and two levels of blood controls. In both studies, less than 5% of CV was obtained indicating good lot-to-lot consistency and between instrument precision.

Comparison Study Summary

Human whole blood samples were tested with the SMART HbA1c Assay and results obtained were compared to the predicate method. A total of 64 samples ranging from 4-12% HbA1c were tested in both assays. The above described accuracy study showed that the SMART HbA1c assay results correlated well with predicate method with a correlation coefficient of 0.96 with a slope of 0.94 and 0.30 intercept.

	Whole blood application
n	64
Slope	0.96
Intercept	0.30
Correlation coeffi-	0.94
Range of values	4.5% - 11.1% HbA1c

Interference Study Summary

The following substances normally present in the blood produced less than 10% deviation when tested at levels equal to the concentrations listed below:

Interference	Concentration
Ascorbic Acid	30 mg/dL
Bilirubin	15 mg/dL
Bilirubin Conjugate	5 mg/dL
Uric Acid	30 mg/dL
Triglyceride	4000 mg/dL
Glucose	5,000 mg/dL
Urea	100 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Diazyme Laboratories
c/o Dr. Abhijit Datta, Director, Technical Operations
12889 Gregg Court
Poway, CA 92064

APR 2 6 2010

Re: k092911
Trade Name: SMART HbA1c Assay Reagent Kit, SMART HbA1c Assay Control Kit, SMART Analyzer
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Codes: JJX, JJE
Dated: March 18, 2010
Received: March 22, 2010

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If Known): k092911

Device Name: SMART HbA1c Assay Reagent Kit, SMART HbA1c Assay Control Kit, SMART Analyzer

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092911